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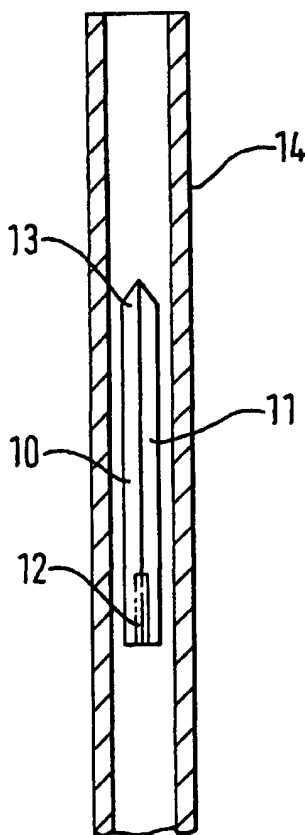
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(54) Title: **DEVICE FOR THE REPAIR OF ARTERIES**



(57) Abstract: A device is provided for piercing a graft and artery wall in order to retain the graft on the artery. The device has a central section with an abutment surface for contacting the inner wall of the graft and two elongate members with distal ends for contacting the outer wall of the artery when the device is pierced through the graft and artery. The elongate members are biased so as to urge the abutment surface into the graft and retain the graft on the artery.

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Device for the Repair of Arteries

The present application relates to a device for retaining a graft on an artery, and in particular to a device which can be used surgically to join living tissue or to attach graft
5 material to living tissue. More specifically, it can be used to join a vascular graft to an artery wall, preferably by minimally invasive or endolumenal means.

WO 92/05828 discloses a wire-form suture which comprises an open wire ring, the ends of which have been arranged to overlap. The wire-formed ring can be fully or partially
10 straightened, one end sharpened and the whole device driven through adjoining tissues. The wire has a spring or shape memory characteristic which causes it to re-form into a ring shape when in place thereby drawing together the tissues.

An improvement to this design is disclosed in WO 00/07506 (in the name of the present
15 applicant – published after the priority date of the present application), in which a pair of joined wires have a shape memory which causes them to form an 'H' shape upon deployment. This shape has the advantage of symmetry which ensures that the orientation of the device remains stable after implementation. It also has the advantage that the overall width of the device increases after implantation. This reduces the
20 possibility of the device's pulling out from its implantation site. Both of these advantages are particularly important in the critical application of intra-arterial implantation.

A requirement of the design disclosed in WO 00/07506 is that the part of the device where the wires are attached to each other is intended to lie within the wall of the artery
25 and the graft with the divided parts of the device projecting beyond the artery walls and graft on both the lumenal and the visceral sides. A consequence of this requirement is that the paired wires must remain in contact with each other along their lengths while they pass through the artery and graft. If they do not, then the device may not pass fully through the structures or the device may remove a core of material (due to its increased
30 width). This constrains the design of an appropriate delivery system and can increase the risk of misplacement of the device. Such misplacement could have serious consequences

for a patient.

According to a first aspect of the present invention, there is provided a device for retaining a graft on an artery, which device comprises a central section having an abutment surface and two elongate members extending from the central section, the
5 elongate members being resiliently biased into a open configuration in which the ends of the elongate members distal from the central section are spaced apart from one another, wherein the elongate members can be moved against said bias into a closed configuration in which said distal ends are closer together than in the open configuration, wherein said
10 distal ends are adapted to pierce the graft and the artery wall when the device is in the lumen of the artery, so that the elongate members can be urged through the graft and artery wall in order to bring the abutment surface into contact with the graft, such that in use the graft is retained on the artery between said abutment surface and the distal ends of the elongate members with the resilient bias of the elongate members urging the
15 abutment surface against the graft.

By graft is meant any material used to repair or support damaged or weak conduits within a living organism, including arteries and veins. The graft may be formed from nature tissue or from woven, moulded or extruded synthetic polymeric or elastomeric
20 materials and may be tubular or flat (i.e. a patch). It may include a stent i.e. may be a stent-graft.

The provision of an abutment surface which remains inside the lumen of the artery has the advantage that the elongate members can move apart from each other into the open
25 configuration as they advance through the graft and artery walls, because there is not the risk that a core of graft or artery will be removed as in the prior art. In a particularly preferred embodiment, there are no projections from the central section which remain in the lumen of the artery when the device is in place, so that minimal obstruction is caused to fluid flow through the artery.

In a preferred embodiment the device is formed from elastic wire, the central section being formed from a loop in the wire, wherein an external surface of the loop forms the abutment surface. The loop is preferably formed from half to two, and most preferably about one and a half, turns of said wire.

5

The provision of a loop is an efficient and elegant mechanical solution, in that it enables the device to be formed from a single piece of wire; it provides for the biasing of the elongate members; it provides an abutment surface which curves away from the graft wall to reduce damage; and it provides a place on the device for the attachment of a
10 suture to enable the device to be repositioned within the artery lumen.

In a particularly preferred embodiment, the loop is formed so that moving the elongate members into the closed position closes the loop. This increases the resilient bias of the elongate members and avoids unwrapping the loop when the device is moved into the
15 closed configuration.

The elongate members may be disposed approximately on the same plane when the device is in the open configuration, and the construction of the device is preferably such that the minimum angle between a vector from the central section to one of said distal
20 ends and a vector from the central section to the other of said distal ends when the device is in the open configuration is from 150 to 180°. Clearly, when the device is in use pierced through the graft and artery, it is likely to be disposed somewhere between the closed and the open configurations, depending on the thickness of the graft and artery walls.

25

According to a second aspect of the present invention, there is provided a method for retaining a graft on an artery, comprising providing a device as defined above, moving the elongate members into the closed configuration, conveying the device along the artery until it is inside the graft, driving the distal ends of the elongate members into the
30 graft and then the artery such that the elongate members move away from the closed configuration and towards the open configuration as they pierce the graft and artery, and

continuing to drive the device through the graft and artery until the abutment surface abuts the graft wall, whereby the graft is retained on the artery by the device. The device is preferably conveyed along the artery in a catheter with the distal ends of the elongate members leading and the central section following.

5

The improved design disclosed here reverses the requirement of PCT/GB99/02544 so that the paired members of the device are separate as they pass through the walls of both the graft and the artery and they remain separate on the visceral side of the artery. A further improvement is that the part of the device where the paired members are

10 connected lies within the lumen of the artery rather than in its wall. As a consequence there is no requirement of the delivery system to retain the paired members of the device in contact. Neither is there a requirement for a single, large hole to be made in the wall of the artery in which the joined part of the paired members can lie. In these ways the improved design makes successful delivery more likely and reduces the risk of damage to
15 the artery wall.

The device may be constructed from a number of materials including metals and plastics and it may be fabricated from separate components, cut from a single block of material, moulded, cast or otherwise constructed.

20

Typical dimensions of the preferred embodiment are as follows:

DIMENSION	MAXIMUM	MINIMUM	PREFERRED
Wire Diameter	1.0mm	0.1mm	0.5mm
Wire Length	50mm	4mm	25mm

25 As stated above, it is preferred that the device be formed from a single wire with a loop. In an alternative embodiment, however, the device comprises at least two wires which can be constrained to be parallel, each wire having two ends, the wires being joined together at or near to one end by welding, braising or similar means. The second, free

ends of the wires are sharpened with a bevel, trocar, bullet, conical, diamond or similar point. The wires may be fabricated from a material which has a spring or thermal or super-elastic shape memory such as nickel/titanium shape memory alloy such that their unconstrained shape is a curved 'Y' or 'gull-wing' shape in which the base of the 'Y' is formed from the joined wires, forming the abutment surface.

Typical dimensions of this embodiment are as follows:

DIMENSION	MAXIMUM	MINIMUM	PREFERRED
Wire Diameter	1.0mm	0.1mm	0.5mm
Weld Length	5mm	1mm	2mm
Wire Length	25mm	4mm	8mm

10

In use, the device may be pushed through a tube with its sharpened ends arranged to emerge first from the tube. The tube constrains the wires of the device to be almost parallel but ensures that the points of the wires are slightly separate before they penetrate the tissue. The device is ejected progressively from the tube and the sharpened tips of the device are driven by spring recoil or thermal shape recovery to become further and further apart as the device emerges from the tube. When used to attach a vascular graft to an artery wall after delivery from within the artery, the device is disposed so that the welded join lies within the lumen of the artery and the sharpened tips of the device have penetrated both the device and the wall of the artery and have curved away from the midline of the device.

20

The connection between the wires can include a sleeve which supplies strength, radio-opacity and a mechanical stop to prevent the device from passing through the wall of the artery.

25

A number of preferred embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 depicts schematically the prior art device of PCT/GB99/02544;

Figure 2 depicts one embodiment of a device according to the present invention
5 constrained within a delivery tube;

Figure 3 shows a perspective view of the device of Figure 2 when open;

Figure 4 is a sectional view of the device of Figures 2 and 3 implanted through a
10 vascular graft and the wall of an artery;

Figure 5 is a perspective view of an alternative device according to the invention;

Figure 6 shows a sectional view of a further alternative device according to the invention
15 implanted through a vascular graft and the wall of an artery;

Figure 7 shows a preferred embodiment of the present invention; and

Figure 8 is a sectional view of the device of Figure 7 constrained within a delivery tube.
20

Turning to the drawings, Figure 1 shows a prior art fixator 1 (as disclosed in WO
00/07506) having a central section 2 and four legs 3. In Figure 1A, fixator 1 is correctly
positioned across artery wall 4 and graft wall 5, with central section 2 being implanted in
artery wall 4. This position arises from the leading legs 3 having passed through graft
25 wall 5 and artery wall 4 together, only separating after they have emerged from artery
wall 4.

Figure 1B shows the incorrect placement of fixator 1 resulting from paired legs 3
separating while passing through artery wall 4. It can be seen that, if fixator 1 is
30 advanced any further, a core of material from graft wall 5 and then artery wall 4 will be
removed by fixator 1.

Figures 2 to 4 show an embodiment of the present invention, in which fixator 10 has two legs 11 which are welded together at boss 12 and which terminate at sharpened ends 13. Legs 11 are resiliently biased into the splayed configuration shown in Figure 3, but can
5 be bent towards each other so as to lie in the generally axial configuration shown in Figure 2, in which fixator 10 is constrained within delivery catheter 14.

Figure 4 shows fixator 10 in use, with graft 5 retained on artery wall 4 between boss 12 and ends 13 of fixator 10. It can be seen that legs 11 have separated into the open splayed configuration on passing through graft 5 and artery 4.

10

Figure 5 shows an alternative fixator 20 formed from a single resilient wire which is bent into a "gull wing" shape with two legs 21 depending from central section 22 and terminating in sharpened ends 23. It will be appreciated that fixator 20 functions in much the same way as fixator 10 of figure 3.

15

Figure 6 shows a further alternative fixator 30 in place retaining graft 5 on artery 4. Fixator 30 has two legs 31 connected at boss 32 by a sleeve made from a radio-opaque material. This enables fixator 30 to be located and tracked by a surgeon. Legs 31 terminate in sharpened ends 33 as before.

20

A surgical fixator 40 for attachment of material to body tissue is shown in Figures 7 and 8. Fixator 40 is formed from a length of highly elastic wire and comprises a looped portion 42 and two leg members 41. The ends 43 of the leg members are sharpened. Looped portion 42 is a coil of about 1.5 turns. Leg members 41 extend tangentially from
25 each end of looped portion 42 in a generally arcuate form. The centre of legs members 41 are a few millimetres either side of looped portion 42 and at the top of the arc, so that a tangent connecting both arcs is a distance of a few millimetres from the looped portion. The planes of the arc formed by the leg members 41 are generally parallel. The leg members are sharpened to conical points 43. Leg members 41 are generally semi-
30 circular in shape.

Fixator 40 can be elastically deformed so that leg members 41 are folded together and constrained inside a catheter 14 as shown in Figure 8 with ends 43 of leg members 41 pointing to the distal end of catheter 14. Inside catheter 14 is slideably mounted a positioning tube 50 next to loop 42. The inner bore of positioning tube 50 is smaller
5 than the width of loop 42, so that loop 42 cannot enter positioning tube 50. Also, positioning tube 50 is longer than catheter 14, and can be moved by adjusting the position of the end 51. A length of flexible suture 70 is threaded through loop 42 and positioning tube 50, with two ends suture 70 protruding from positioning tube 50 and connecting together to form a handle 71. The position of fixator 40 relative to catheter
10 14 can be adjusted by a combination of pushing on positioning tube 50 and pulling on handle 71.

Fixator 40 is used to fix two sheet materials together by positioning the distal end of catheter 14 against and substantially perpendicular to the two materials. Fixator 40 is
15 advanced through catheter 14 by pushing positioning tube 50, until tips 43 of legs 41 protrude and penetrate the materials producing a small aperture. Fixator 40 is then advanced further, and legs 41 will travel through the aperture. Once through the materials legs 41 will resume their arcuate form (the open configuration). The two materials are then retained together between loop 42 on one side and ends 43 of legs 41
20 on the other side. Suture 70 is removed by pulling one of its ends.

CLAIMS

1. A device for retaining a graft on an artery, which device comprises
a central section having an abutment surface and two elongate members extending
5 from the central section, the elongate members being resiliently biased into a open
configuration in which the ends of the elongate members distal from the central section
are spaced apart from one another,
wherein the elongate members can be moved against said bias into a closed
configuration in which said distal ends are closer together than in the open configuration,
10 wherein said distal ends are adapted to pierce the graft and the artery wall when
the device is in the lumen of the artery, so that the elongate members can be urged
through the graft and artery wall in order to bring the abutment surface into contact with
the graft,
such that in use the graft is retained on the artery between said abutment surface
15 and the distal ends of the elongate members with the resilient bias of the elongate
members urging the abutment surface against the graft.
2. A device as claimed in claim 1 additionally comprising means for attaching a
suture.
20
3. A device as claimed in claim 2, wherein said means is a loop formed in the
central section.
4. A device as claimed in any preceding claim, wherein the device is formed from
25 elastic wire, the central section being formed from a loop in the wire, wherein an
external surface of the loop forms the abutment surface.
5. A device as claimed in claim 4, wherein said loop is formed from half to two
turns of said wire.

6. A device as claimed in claim 4, wherein said loop is formed from about one and a half turns of said wire.

7. A device as claimed in any of claims 4 to 6, wherein said loop is formed so that
5 moving the elongate members into the closed position closes the loop.

8. A device as claimed in any preceding claim, wherein the elongate members are disposed approximately on the same plane when the device is in the open configuration.

10 9. A device as claimed in any preceding claim, wherein the minimum angle between a vector from the central section to one of said distal ends and a vector from the central section to the other of said distal ends when the device is in the open configuration is from 150 to 180°.

15 10. A device as claimed in claim 9, wherein said angle is about 180°.

11. A device as claimed in any preceding claim, wherein said abutment surface is curved away from the graft wall with which it makes contact in order to minimise damage to the graft.

20

12. A device as claimed in any preceding claim, wherein there are only two elongate members extending from the central section.

13. A device for retaining a graft on an artery, comprising an abutment portion for
25 abutting the graft wall, and two elongate members extending from the abutment portion, the ends of the elongate members distal from the abutment portion being adapted to pierce the graft and the artery wall, the elongate members being resiliently biased into a retaining configuration such that in use the graft is retained on the artery between the abutment portion and the distal ends of the elongate members, and the elongate members
30 being moveable into an axial configuration in which said members are disposed substantially on an axis, to enable the device to be conveyed along an artery.

14. A device as claimed in claim 13, wherein the abutment portion includes means for attaching a suture.

5 15. A device as claimed in claim 14, wherein said means is a loop formed in the abutment portion.

16. A method for retaining a graft on an artery, comprising providing a device as claimed in any of claims 1 to 12, moving the elongate members into the closed
10 configuration, conveying the device along the artery to a locus of the graft wall, driving the distal ends of the elongate members into the graft and then the artery such that the elongate members move away from the closed configuration and towards the open configuration as they pierce the graft and artery, and continuing to drive the device through the graft and artery until the abutment surface abuts the graft wall, whereby the
15 graft is retained on the artery by the device.

17. A method as claimed in claim 16, wherein the device is conveyed along the artery in a catheter with the distal ends of the elongate members leading and the central section following.
20

18. A method as claimed in claim 16 or 17, comprising the additional steps of attaching a suture to the device prior to conveying the device along the artery and removing the suture after the graft has been retained on the artery by the device.

25 19. A method as claimed in claim 18, additionally comprising the step of repositioning the device on the graft wall either before or after the graft wall has been pierced by the elongate members by drawing on the suture to move the elongate members towards the closed configuration.

30 20. A method for retaining a graft on an artery, comprising providing a device as claimed in any of claims 13 to 15, moving the elongate members into the axial

configuration, conveying the device along the artery until it is inside the graft, driving the distal ends of the elongate members into the graft and then the artery such that the elongate members move away from the axial configuration and towards the retaining configuration as they pierce the graft and artery, and continuing to drive the device

5 through the graft and artery until the abutment portion abuts the graft wall and the device is in the retaining configuration.

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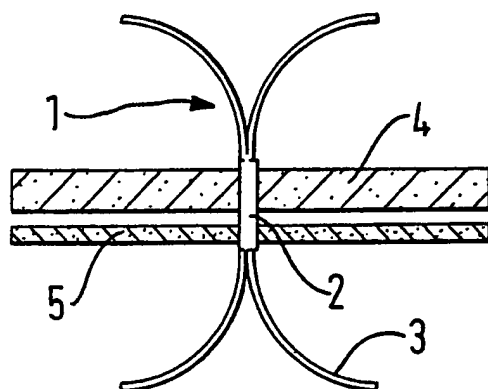


FIG. 1A

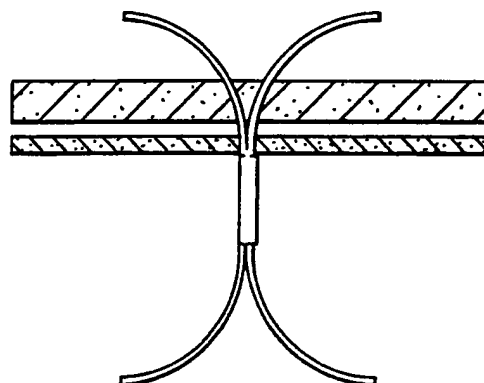


FIG. 1B

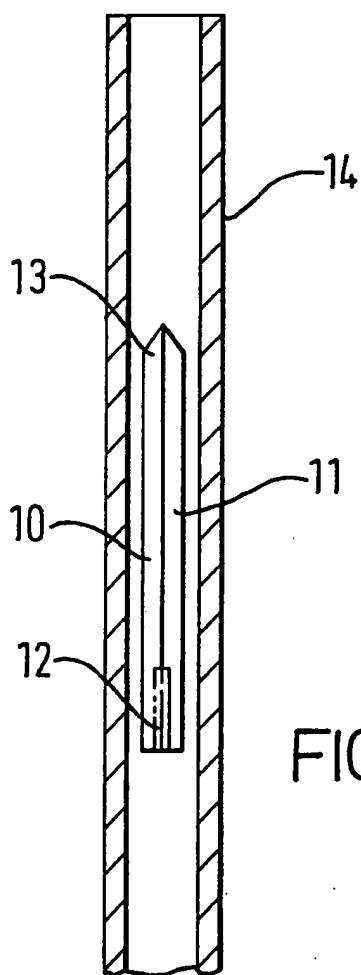


FIG. 2

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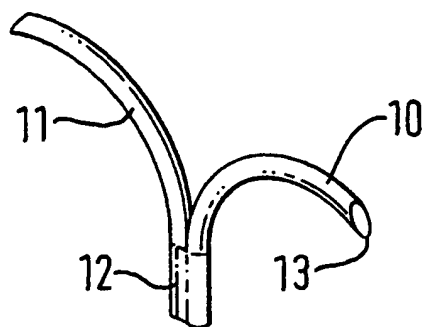


FIG. 3

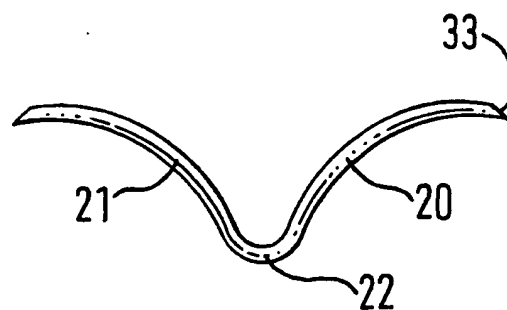


FIG. 5

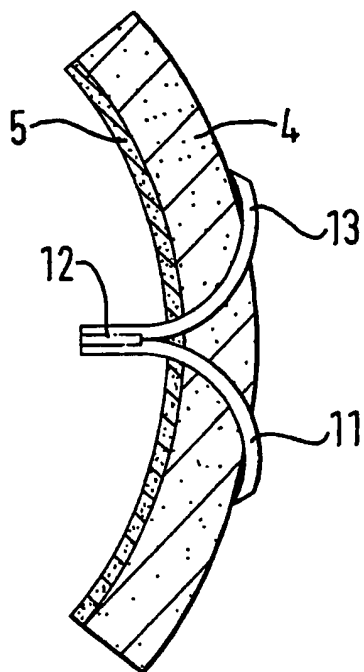


FIG. 4

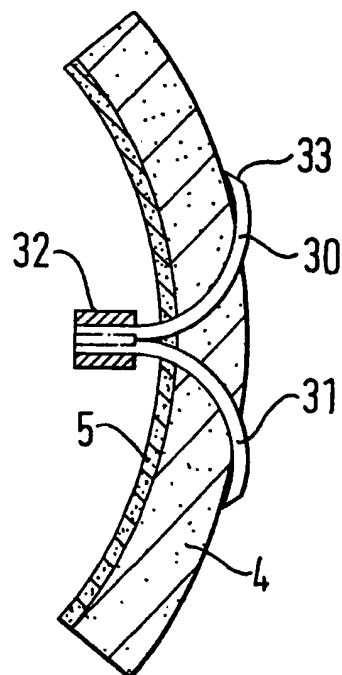


FIG. 6

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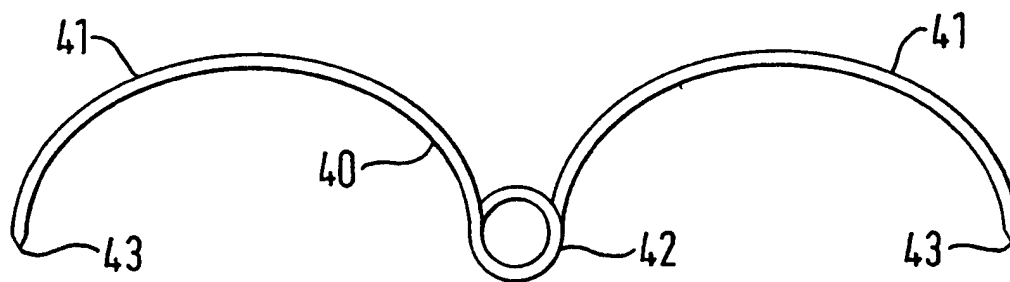


FIG. 7

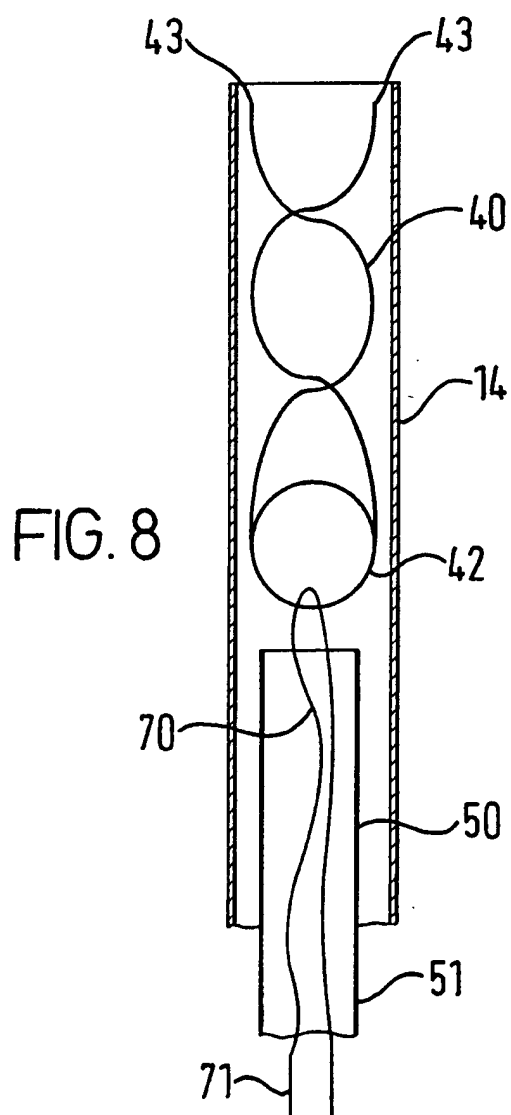


FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/064

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 5 720 755 A (DAKOV PEPI) 24 February 1998 (1998-02-24) column 16, line 56 - line 66; figures 27A,27B	1,8-13
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

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